

REMARKS

Claims 1 to 12 are pending in this application. Claims 10 and 12 are new. Claims 1 and 11 are independent. Claims 1 to 10 stand rejected under 35 U.S.C. § 102(b) and/or § 103(a) in light of U.S. Pat. No. 5,308,483 (the "Sklar reference"), U.S. Pat. No. 5,227,062 (the "Olsen reference"), and/or U.S. Pat. No. 5,948,246 (the "Zuk reference"). Applicant disagrees.

Applicant's invention provides a fluid-filtration receptacle well suited for various sample concentration protocols, particularly those protocols wherein a specifiable degree of sample concentration is sought. Toward such ends, the fluid-filtration receptacle is provided with an integrated semi-permeable drain capable of being either completely or variably unsealed by a user to allow the selective draining of a predetermined corresponding volume of said liquid from said receptacle. The fluid-filtration receptacle is preferably used in combination with a filtrate collection vial. The receptacle fits at least partially within the vial such that liquid (*i.e.*, filtrate) drained from said receptacle collects within said vial.

The Sklar reference is directed to a filter holder; the Olsen reference, to a valve; the Zuk reference, to a vacuum filter assembly. None are directed to a volume-specifiable receptacle. To the extent that applicant's original claims may or may not have admitted interpretations that beg comparison to such devices, applicant's subject matter employs different means toward different objectives, and hence remains unforeseen by any cited art references, alone or in combination, more so in view of the amendments herein.

Claims 1 and 3 to 9 are amended. Informalities spotted in the specification are fixed *sua sponte*. No "new matter" is added.

Applicant requests reconsideration.

35 U.S.C § 102(b) -- Olsen Reference

Original claims 1 to 3 stand rejected under 35 U.S.C. § 102(b) as anticipated by the Olsen reference. The examiner states, "Olsen discloses receptacle 14 or 19, partially enclosed by solid material 34 having a drain portion with plural drain openings 38 or 35/42 and a device to **partially or completely unseal** the openings 25/28/48." (Emphasis added). Applicant disagrees.

The Olsen reference is drawn a valve that regulates water flow by variably aligning corresponding patterns of orifices provided on two adjacent rotating plates. The plates are adjustable between a position in which the orifices are totally unaligned (to prevent passage of fluid) and a position in which the orifices are fully aligned (to allow maximum passage of fluid). The application emphasized in the Olsen reference for the valve is within a "fluid separation system of the type having a pressure feed, a fluid separation portion and a flow control passage".

At the outset, applicant appreciates the examiner's broad construction of applicant's "seal component", and agree that such "seal component" should not be limited to the specific embodiments set forth in applicant's specification. Applicant by his present claims does intend to encompass "seal components" that -- like the Olsen device -- operate by the displacement of a

physical barrier (e.g., a sliding or rotating gate) to the flow of fluid. Regardless, though the "seal component" is literally shown by the Olsen reference, an important substantive distinction remains.

In particular, the Olsen reference does not teach the "draining of a predetermined corresponding volume" of liquid by the removal (completely or variably) of a "seal component". As stated in applicant's specification: "[I]t is a principal object of the present invention to provide a fluid-filtration receptacle capable of filtering **specifiable** volumes of a sample liquid". (Page 5, line 21 to 23, emphasis added). The Olsen reference discloses a "valve". The valve is not intended to filter specifiable volume of fluid.

It is understood that the "no volume" (i.e., unaligned orifices) extreme attainable by Olsen's valve is technically a "predetermined" volume. But, this "no volume" extreme isn't accomplished by any removal (completely or variably) of any seal component. It is accomplished by leaving in place the unaligned orifices. When Olsen's orifices (i.e., the "seal component") are rotated into alignment (i.e., "unsealed"), the fluid volume pumped therethrough is continuous, not "predetermined". If there is a set quantitative volume of fluid released when the Olsen device is in its open state, it is set as a function of pump 13, not Olsen's "seal component".

To further emphasize applicant's fluid filtration receptacle as a volume-specifiable receptacle, applicant amends claim 1 to denote that the inventive "fluid-filtration receptacle" bears volume-related "informative indicia". No such "informative indicia" -- as that term would be understood to those "skilled in the art" (e.g., volume legends, text, symbols, color codes, and the like -- can be found in the Olsen reference, or any cited art reference of record. The "informative indicia" recitation is felt fitting for the present invention. Such indicia -- aside from being a tangible, probative limitation -- would only be used in a fluid filtration receptacle wherein the objective of providing a "seal component" is to enable user-specifiable filtered drainage of the indicated predetermined volume of fluid. The recitation adequately distinguishes applicant's invention, while encompassing broadly the practical embodiments thereof.

No "new matter" is added. Indicia is shown, for example, throughout the Figures. Antecedent basis for the use of the informative indicia "proximate" the seal can be found, for example, at page 9, lines 26 to 29. Basis for the use of informative indicia "on" the seal component can be found, for example, in Fig. 3.

Claim 1 is felt novel in light of the Olsen reference. Withdrawal of the Section 102 rejection as applied to claim 1 is requested.

Regarding dependent claim 2, the examiner states: "[t]he claim is reciting membrane *material*, most materials being capable of use as a membrane; if necessary, Olsen discloses upstream membrane (column 4, lines 13-17)." Applicant disagrees. While it is true that the universe of materials useful for making "membranes" is vast, it remains questionable whether the Olsen reference discloses a "semi-permeable membrane material" that is "positioned within or superposed over" a drain "opening". The "upstream membrane" is far removed from Olsen's "orifices", and hence irrelevant. If the argument then is that the pattern of Olsen's orifices has a separation function comparable to a membrane's separation functionality (i.e., the "orifices" are the "membrane"), there is nothing in the Olsen reference that discloses the drain "opening". And, if the orifices are to be

construed as applicant's "openings", there is no disclosure of a "membrane". Essentially, the orifices can only be used to construe either the "opening" or the "membrane". They can not be used soundly to construe both. Regardless, claim 2 is dependent on claim 1. Withdrawal of the Section 102 rejection as applied to claim 2 is requested.

Regarding claim 3, the examiner states: "[T]he claim is merely reciting *openings*, per se, not structure for individually sealing or unsealing the openings". Claim 3 is amended. Structural recitations are provided. Claim 3 is dependent on claim 1. Withdrawal of the Section 103 rejection as applied to claim 3 is requested.

35 U.S.C § 102(b) -- Sklar Reference

Original claims 1, 2, and 4 to 10 stand rejected under 35 U.S.C. 102(b) as anticipated by the Sklar reference.

The Sklar reference is directed to a two-part filter holder of the type commonly seen in laboratories. Sklar's filter holder comprises a reservoir, an interlocking filter base, and a membrane interposed therebetween. The filter holder can be disassembled and differentially reassembled so that the membrane can be positioned, moved, and/or otherwise prepared for culturing or identification or analysis of filtered material.

The examiner states, "Sklar et al disclose a sampling and filtering assembly comprising a receptacle with a fillable internal area (upper body 10), capable of use in plural positions or orientations, such as inverted positions (column 4, lines 3-29), impermeable solid area 34, having drain 42 and variably sealing and unsealing member 43 or 50 (see generally column 3, lines 12-45)." .

Applicant appreciates the examiner's observation. Regardless, as stated above, claim 1 is amended to further underscore the volume-specifiable functionality of applicant's receptacle, in part by reciting its "informative indicia". This feature -- as the case with the Olsen reference -- is not disclosed by the Sklar reference. Withdrawal of the Section 102 rejection as applied to claim 1 is felt appropriate.

As to the balance of the rejected claims, claims 2, 4 to 8, and 10 were grouped together and rejected collectively by the examiner's identification in the Sklar reference of a "single drain opening 41, and membrane 37". Claims 2, 4 to 8, and 10 are each ultimately dependent on claim 1. Claim 1 is felt novel. Likewise, claims dependent thereon are also felt novel.

Moreover, claim 4 is amended to recite that applicant's drain comprises a "single, sealed, semi-permeable opening" and that the "seal component comprises a plurality of independently removable seals" and that the "single opening [is] capable of being variably unsealed by a user by removal of one or many of said independently removable seals". The Sklar reference does not disclose such structure or such functionality.

Claims 6 to 8 define more specifically applicant's "seal component": *i.e.*, a "removable thermoplastic covering", a "removable elastomeric coating", and a "thin user-destructible thermoplastic film", respectively. These claims were rejected with reference to Sklar's "thermoplastic seal covering 50 of gasket or resilient construction, (column 3, lines 12-16 and 42-45 and column 4,

lines 35-36)". Applicant disagrees. Neither cap 50 nor outlet closure 43 disclose an "elastomeric coating" (claim 7); nor do they disclose the dimensional recitations set forth in claim 8, *i.e.*, "user-destructible" and "average thickness substantially less than the average thickness of said liquid-impermeable solid material". With respect to claim 6, applicant refers to the added "informative indicia" recitation, and notes that in Sklar's example (col. 4), "outlet closure 43" is used to cap "outlet port 41" after filtration occurs.

Claim 9 (and claim 10) is directed to a "centrifugal filter unit kit" that includes "the fluid-filtration receptacle of claim 1" and "a filtrate collection vial", wherein the receptacle is "at least partially fittable" within vial. The examiner rejected the claim, referring to "the uses described in column 3, lines 46-49 and column 4, lines 1-29[, which] define the apparatus as a kit". Claim 9 is dependent on claim 1. Claim 1 is felt novel. Likewise, dependent claim 9 is also felt novel.

Moreover, though Sklar's filter holder arguably combines two "fittable" components -- *i.e.*, a funnel 10 and a base 30 -- the examiner's preceding arguments combined these two components as a single entity to find "all limitations" of applicant's claim 1. It would be inconsistent to now separate these components conceptually and argue that the funnel base 30, for sake of rejecting dependent claim 9, should be interpreted as a "filtrate collection" vial. To the extent that other like paired components can be extrapolated from the Sklar reference, a rejection based on such combination would probably also suffer in respect of consistency.

35 U.S.C. § 103(a) -- Sklar and Zuk References

Original claim 3 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the Sklar reference in view of the Zuk reference. Independent Claim 1 is amended to add a recitation to "informative indicia". Claim 3 -- aside from being amended herein to improve clarity -- remains dependant on claim 1. The amendment to independent claim 1 renders moot the grounds for rejecting dependent claim 3. Withdrawal of the rejection as it relates to claim 3 is requested.

The subject matter originally targeted by claim 3 is now the focus of new claims 11 and 12. To the extent that the grounds for rejecting claim 3 would be relevant also to new claims 11 and 12, the Sklar and Zuk references are discussed further below.

New Claims 11 and 12

New claims 11 and 12 are drawn to embodiments of the present invention represented by the receptacles illustrated in Figs. 1 to 4. In particular, the claims are directed to the use of several drain holes, each covered by individual seals, each corresponding to individual predetermined fluid drainage levels. The structure is not disclosed in any cited art reference. None disclose or suggest sealing a plurality of drain holes with independently removable seals.

New claim 11 is *not* original claim 3 rewritten in independent form. Substantive differences do exist. Regardless, the targeted subject matter is similar.

As to original claim 3, the examiner observed that the Sklar and Zuk references disclose assemblies comprising "membrane filters for samples, filtrate reservoirs, funnels, and reusable bases"; and that "Zuk teaches plural openings 52 or 58 at membrane support above the

reservoir (column 3, lines 43-54)." The examiner concluded: "It would have been obvious to one of ordinary skill in the art to have modified the Sklar et al arrangement by providing plural, rather than a single, drain opening, as taught by Zuk, so as to collect larger quantities of filtrate, at a higher, more accurate flow rate."

The examiner's analysis when applied to original claim 3 had shortcomings, and should not now be applied to new claims 11 and 12. In particular, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. In the instant case, there is no basis for combining the Sklar and Zuk references.

Both the Sklar and Zuk references each disclose a number of structural features, some similar, others different. Included among these features, for example, are inlets, outlets, reservoirs, rims, drain ports, gaskets, membranes, guide ribs, slots, funnels, filter pads, caps, plugs, tubing, inner wall surfaces, circular ribs, beads, "poppet" valves, grooves, O-rings, notches, ports, side tubes, and many other structural elements. These structural elements vary in shape, size, functionality, and arrangement. The potential number of varying devices that can be assembled by interchanging and combining the structural element(s) of one reference into the other is vast. Applicant question then the likelihood that one reasonably skilled in the art, ignorant of applicant's invention, would have decided to reconfigure Sklar's single-opening funnel outlet to provide it with several discrete openings, as shown in the Zuk reference. The incentive proffered by the examiner, *i.e.*, to increase flow rate, is questionable. The flow rate would likely be diminished by such reconfiguration.

Moreover, if combined, the two references still do not disclose or suggest the instant invention. New claims 11 and 12 are not differentiated from the prior art solely on the basis of multiplicity of outlets. That is old. Rather, new claims 11 and 12 recite also "a plurality of independently removable seals" that releasably-seal a corresponding "plurality of discrete semi-permeable openings". The claims recite that the seals can be "completely and independently removed" to allow "draining of corresponding predetermined volumes of ... liquid from [the fluid filtration receptacle's] internal area". Such features, relationships, and functions are not taught by any cited art reference of record, alone or in combination.

CONCLUSION

The pending claims define subject matter neither described nor suggested by the cited art references. The written description and claims meet all applicable statutory requirements. The application is in condition for allowance.

Respectfully submitted,



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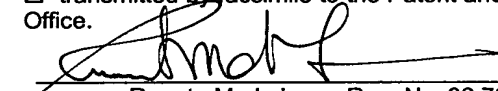
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